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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Jacques-Pierre Moreau
Serial No. : 09/744,846
Filed : January 30, 2001
Title : METHODS OF USING A SOMATOSTATIN ANALOGUE

Art Unit : 1631
Examiner : M. Borin

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Commissioner for Patents
Washington, D.C. 20231

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RESPONSE TO OFFICE ACTION

Responsive to the action mailed September 20, 2002 (the "Action"), Applicant requests consideration of the following remarks. Claim 5 is pending.

Rejection under 35 U.S.C. 102(b)

Claim 5 is rejected as anticipated by Coy et al. (US 4,853,371) or Bogden (US 5,411,943). It is alleged that Coy teaches a pharmaceutical composition comprising a therapeutically acceptable amount of β -Nal-Cys-Tyr-D-Trp-Lys-Val-Cys-Thr-NH₂ (hereinafter "Compound") or its pharmaceutically acceptable salt (including its acetate salt). It is also alleged that Bogden teaches use of β -Nal-Cys-Tyr-D-Trp-Lys-Val-Cys-Thr-NH₂, including as its acetate salt, for hepatoma treatment. It is then concluded in the Action that the pharmaceutical compositions of Coy or Bogden anticipate Applicant's composition of pending claim 5. Applicant disagrees with this conclusion.

Claim 5 recites a composition comprising an effective of amount of the acetate salt of Compound to treat the delineated diseases or conditions. Thus, the diseases and conditions recited provide guidance for the amount of Compound acetate salt present in the composition. This guidance is distinct and distinguishable from the recitation of the diseases or conditions in the claim being construed as "intended use" of the composition. In other words, the

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disease/conditions listing in claim 5 is not an intended use as seen in *In re Pearson* 494 F.2d 1399; 181 USPQ 641 (CCPA 1974). Rather, it is part of the delineation of the amount (i.e., that effective to treat a listed disease/condition) of Compound acetate salt in the composition of claim 5. Furthermore, the Court stated in *In re Pearson* that "[w]e do not mean to imply that terms which recite the intended use or a property of a composition can never be used to distinguish a new from an old composition." (494 F.2d 1403, 181 USPQ 644), thus indicating that there are circumstances where it would be appropriate to recite intended use. Nonetheless, the listing of diseases and conditions in Applicant's claim 5 are not merely "intended use" in the sense of *In re Pearson*. Such listing relates to the amount of Compound acetate salt in the composition.

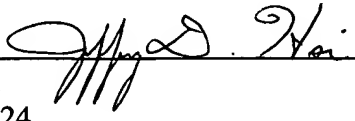
It is established that "[A] claim is anticipated only if each and every element as set forth in the claim is found, whether expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Here, claim 5 recites that the amount of Compound acetate salt present in the composition need be that which is effective for treating the delineated disease or condition. As the treatment of the diseases and conditions recited in claim 5 are not taught by Coy or Bogden, it follows that the effective amount of Compound acetate salt to treat such diseases or conditions is also not taught. Thus, Coy or Bogden do not teach each and every element of the claim and neither Coy nor Bogden are anticipatory of Applicant's claim 5.

In light of the foregoing, Applicant respectfully requests withdrawal of the rejection and allowance of claim 5.

Please apply any charges or credits to Deposit Account No. 06-1050, referencing attorney docket number 00537-182002.

Respectfully submitted,

Date: March 20, 2003



Jeffrey D. Hsi
Reg. No. 40,024

Fish & Richardson P.C.
225 Franklin Street
Boston, Massachusetts 02110-2804
Telephone: (617) 542-5070
Facsimile: (617) 542-8906